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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,831	03/16/2007	Jon Sayers	100042.59317US	5825

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	PAPER NUMBER
1649	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,831	SAYERS ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-23, 48, 51, 52 and 54-57, drawn to a modified cytokine ligand polypeptide.

Group II, claim(s) 24-40, 48, drawn to an oligomeric cytokine ligand polypeptide comprising at least two modified cytokine ligands.

Group III, claim(s) 41-46, 48, drawn to isolated nucleic acid molecules, encoding a modified cytokine ligand polypeptide and the vectors and host cells comprising them.

Group IV, claim(s) 41-46, 48, drawn to isolated nucleic acid molecules, encoding an oligomeric cytokine ligand polypeptide comprising at least two modified cytokine ligands and the vectors and host cells comprising them.

Group V, claim(s) 47, drawn to a non-human transgenic mammal transfected or transformed with the nucleic acid of Group III.

Group VI, claim(s) 47, drawn to a non-human transgenic mammal transfected or transformed with the nucleic acid of Group IV.

Group VII, claim(s) 49 and 50, drawn to a screening method designed to generate modified cytokine ligand polypeptides.

Group VIII, claim(s) 53, drawn to a method of treatment comprising administering a modified cytokine ligand.

Group IX, claim(s) 53, drawn to a method of treatment comprising administering comprising an oligomeric cytokine ligand polypeptide comprising at least two modified cytokine ligands.

Group X, claim 53, administering nucleic acid molecule encoding the modified cytokine ligand polypeptide

Group XI claim 53, administering nucleic acid molecule encoding an oligomeric cytokine ligand polypeptide

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

First, according to 37 CFR 1.475, If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c). In this case, claims 1, 41 and 53 (Groups I, IV and VII) represent a product, a process of manufacture and a process of use, respectively. McWherter et al. (Biochemistry, 1999; 38: 4564-4571—on Applicants' 1449 form) teach how to make and use a modified G-CSF wherein the native amino acid and carboxy terminal acid residues are linked through a linker and provided with alternative termini (see for example, p. 4565, right column, last two paragraphs; also p. 4570, right column, last paragraph for the therapeutic potential of the chimeric proteins), thus claims 1, 41 and 53 lack unity ***a posteriori***. In addition, Kreitman et al. (Cytokine, 1995; 7: 311-318—on Applicants' 1449 form) teach a modified IL-4 wherein the native amino and carboxy terminal acid residues are linked through a linker and provided with alternative termini (see for example, abstract; also p. 314, right column, 2nd and 3rd paragraphs). Further the binding domain of the circular IL-4 is located near the C-terminus, and Kreitman et al. teach the disruption of this area at p. 314, right column, last paragraph. Kreitman et al. teach how to make the mutants at p. 312 (whole page, including the nucleic acid molecule, vector and host cells, thus the claims 1 and 41 lack unity ***a posteriori***.

Further, note that claims of Groups I-XI encompass multiple products and processes and 37 CFR 1.475 states the following:

> (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features " shall mean those technical features that define a

> contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
> (1) A product and a process specially adapted for the manufacture of said product; or
> (2) A product and a process of use of said product; or
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
> (4) A process and an apparatus or means specifically designed for carrying out the said process; or
> (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

In the instant case since the claims encompass multiple products, and processes of use, there is more than one of the combinations of categories of invention set forth in paragraph (b) of this section. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

Finally, note that 37 CFR 1.475, part (e) states that "the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim."

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 9:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest

/Bridget E Bunner/
Primary Examiner, Art Unit 1647